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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,327	09/25/2003	William L. Hunter	110129.405C3	5649

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,327

Applicant(s)

HUNTER ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-125 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) See Continuation Sheet is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/8/04, 10/19/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Applicant's election of the femoral artery as a blood vessel, an immunosuppressive agent as an active, a polyester as a polymer a film as a form and a reaction to an operative arterial procedure as a vascular disease in the reply filed on 1/13/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 60-63, 66 and 119-123, 125 have been considered along with elected claims 64 and 123 respectively because vascular disease as a result of angioplasty appears to be applicable to these claims as well.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 20 38, 43-45, 52, 57, 60-64, 66, 67, 70, 74, 75, 79, 97, 101, 103, 104, 111, 116, 119-123, 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman et al in US 5,527,532 in view of Shalaby in 5,612,052 and Babbs et al in 4,978, 668.

Edelman et al teach a method of regulating repair of a tubular structure by extraluminal administration of an agent over a sustained period (abstract). Repairs due to restenosis in the arterial system after angioplasty are disclosed (column 1 lines 39-41). The adventitia is disclosed as an extraluminal site for delivery of the agent from a polymeric formulation (column 3 lines 21-25). Wraps are disclosed as a form for

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delivery of the agent (column 4 lines 31-35). Cyclosporin is disclosed as a immunosuppressant appropriate for carrying out the method (column 4 lines 11-22).

Shalaby teaches an absorbable polyester for controlled release of a biological agent (abstract). Immunosuppressive agents are disclosed (column 10 line 33). Films and sheets are specified (column 13 lines 56-57).

Babbs et al teach balloon angioplasty of femoral arteries (column 2 line 51).

It would have been obvious to one of ordinary skill to use the sheet or film of Shalaby as the wrapping in the method of Edelman et al to achieve the beneficial effect of an absorbable delivery vehicle. As to the claimed femoral artery, Babbs et al teach that balloon angioplasty, after which restenosis can occur according to Edelman et al, is known in the art to be performed on the femoral artery.

Claims 68-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 68 "direction injection" is indefinite; is "direct injection" intended?

Claims 68-69 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. In column 2 lines 32-35 Edelman et al disclose that bolus injections can actually stimulate smooth muscle growth, which is counterproductive to a treatment of restenosis. Thus, it appears that the claimed method is inoperative.

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Claims 68-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because the claimed invention is inoperative, it follows that it cannot be enabled.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 16, 20, 43-45, 52, 57, 60-64, 66-70, 74, 75, 79, 101, 103, 104, 111, 116, 119-123, 125 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,765,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the patented claims regarding the active agent.

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

Continuation of Disposition of Claims: Claims withdrawn from consideration are 17-19,21-37,39-42,46-51,53-56,58,59,65,71-73,76-78,80-96,98-100,102,105-110,112-115,117,118 and 124.

Continuation of Disposition of Claims: Claims rejected are 15,16,20,38,43-45,52,57,60-64,66-70,74,75,79,97,101,103,104,111,116,119-123 and 125.